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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,540	04/15/2005	Stanka Perc	4061-27PUS	1415
27799 7590 05/11/2010 COHEN, PONTANI, LIEBERMAN & PAVANE LLP 551 FIFTH AVENUE SUITE 1210 NEW YORK, NY 10176				
EXAMINER JEAN-LOUIS, SAMIRA JM				
ART UNIT		PAPER NUMBER		
1627				
MAIL DATE		DELIVERY MODE		
05/11/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

<b>Application No.</b> 10/531,540	<b>Applicant(s)</b> PERC ET AL
<b>Examiner</b> SAMIRA JEAN-LOUIS	<b>Art Unit</b> 1627

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 29 March 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See continuation sheet.  
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). filed on 03/30/10  
13. ☐ Other: \_\_\_\_\_.

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1627

The Examiner acknowledges receipt of applicant's arguments and Information Disclosure Statement (IDS) which have been entered into record.

Applicant's argument that Morris emphasizes the criticality of coating olanzapine and thus teaches away from uncoated olanzapine has been fully considered. Additionally, applicant argues that the mottling appearance of air-exposed olanzapine would have taught one of ordinary skill in the art away from formulating uncoated olanzapine. Such arguments are however not persuasive as the Examiner contends that the disclosure of Morris does in fact teach formulations of uncoated olanzapine (see Morris, pg. 4, lines 45-48). While Morris exemplifies a coated olanzapine, the Examiner contends that uncoated olanzapine were also taught by Morris since Morris explicitly teaches that uncoated tablets of olanzapine stored at ambient temperature did not show signs of discoloration thereby suggesting that such formulation can in fact be made and is indeed within the purview of the skilled artisan. While applicant argues that uncoated tablets mean both coated and uncoated tablets, the Examiner contends that nowhere in Morris was it disclosed that uncoated tablets mean both coated and uncoated olanzapine. In fact, based on Morris' disclosure that uncoated olanzapine can be stored for 24 months without discoloration and that when exposed to air discoloration occurs within 5 days, one of ordinary skill in the art would have concluded that such reference is referring solely to uncoated olanzapine. As for applicant's argument that Morris does not teach a homogenous mixture, the Examiner again reiterates the fact that given that the claims are directed to similar formulation as the instant invention, it is incumbent upon applicant to demonstrate through side by side comparison that the prior art is not a homogenous mixture. As a result, the Examiner maintains that the instant claims are indeed rendered obvious by Morris.

Applicant's argument that Chakrabarti does not teach a homogenous mixture but rather a formulation prepared by granulation and compression. Such arguments are however not found persuasive as Chakrabarty teaches that conventional techniques can be used to make olanzapine formulations. While Chakrabarty does not explicitly teach a homogenous preparation, Chakrabarty does teach formulations of olanzapine tablets made according to conventional techniques (including methods of making dry powder formulations) and the use of the same excipients as the instant invention. As a result, the Examiner contends that because Chakrabarty teaches the same components as applicant and teaches the use of conventional techniques to formulate the olanzapine formulations, the instant invention is therefore rendered obvious and a homogenous mixture would have indeed been within the purview of the skilled artisan. Rubinstein, on the other hand, was provided to demonstrate that addition of particular excipients to tablet formulations is well within the skilled of the artisan depending on the properties desired in the tablet formulations. Consequently, the Examiner maintains that Chakrabarty in view of Rubinstein does indeed render obvious applicant's invention.

For the foregoing reasons, the Examiner maintains that the claims were indeed rendered obvious and the rejections are therefore maintained.